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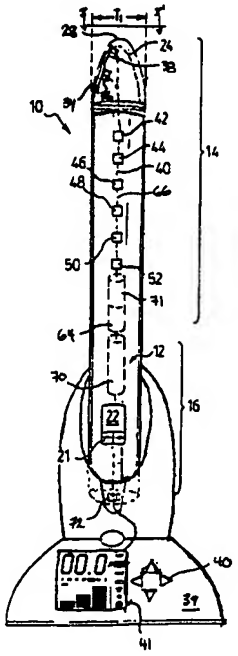
(54) **VAGINAL PROBE HAVING AN IMPROVED SENSOR AND METHOD OF USING SAME**



(57) A probe used to determine different possible body conditions of a human or animal subject includes an elongated insertable portion which is adapted for use orally, anally or vaginally, and along which are provided a number of biosensors and/or temperature sensors. The elongated portion is contoured so as to have a complementary shape to the physiology of the user's mouth, anus or vagina to ensure good contact between the probe sensors and the subject's body fluids or tissues. The probe is used in conjunction with a releasably retained strip medium which provides an indication of a sensed body condition thereon, and one or more sensors used to read the indications on the strip. In use, once the probe is inserted, body fluids will activate the strip medium in vivos ensuring more accurate biosensor readings.

VAGINAL PROBE HAVING AN IMPROVED SENSOR AND METHOD OF USING SAME

SCOPE OF THE INVENTION

The present invention relates to a probe used to determine the status of one or more body conditions of a human and/or animal subject, and more particularly a probe provided with an improved sensor which is adapted for insertion into the subject's mouth, vagina or anus to sense one or more body characteristics indicative of a given body condition, and a method of using such a probe.

BACKGROUND OF THE INVENTION

Vaginal or anal probes which are used to sense or measure a subject's body characteristics to provide an indication of a particular body condition are known. United States Patent No. 5,209,238 to Sundhar, which issued May 11, 1993 discloses one prior art vaginal probe. The probe of Sundhar consists of a cylindrically shaped housing which has positioned therealong a number of longitudinally spaced electronic bio-sensors embedded in the probe surface. In its operation, the probe is used to determine whether or not a human female is ovulating by sensing the state of four body characteristics: basal body temperature; mucous density; pH level; and LH level. As a result of the sensed values, the user is provided with a visual output as to whether or not the received data is indicative of the presence of a viable egg.

The probe disclosed in U.S. Patent No. 5,209,238 suffers certain disadvantages in that for proper operation it is necessary to ensure the positioning of the sensors in close contact with the walls of the user's vagina. If gaps may exist between the user's vaginal tissues and the sensors. This in turn may lead to false sensor readings indicating a user is not ovulating when she may be, or vice versa.

The difficulties associated with the Sundhar probe construction are further compounded if the user's vagina is dry. In such a case, air pockets may exist about the sensors, resulting in poor contact with the sensed vaginal fluids, increasing the likelihood of inaccuracies and misreadings.

In addition, electronic bio-sensors currently available are both costly and limited in the types of body characteristics which may be sensed.

SUMMARY OF THE INVENTION

The present invention seeks to overcome those disadvantages of prior art devices by providing a probe which has a replaceable strip or substrate which is releasably secured to the probe housing to permit the in vitro sensing of one or a number of different body conditions.

A further object is to provide a probe for sensing body characteristics of an animal or human subject and which is adapted for use either orally, vaginally and/or anally.

Another object of the invention is to provide a probe which may be used to sense a condition of human or animal tissues, including diseases or bacteria in meats, liquids, fish or poultry to be used for human consumption.

Another object of the invention is to provide a probe having one or more sensors for sensing a body characteristic which provides an indication of a user's existing body condition, and in which at least one of the sensors is positioned along a surface of the probe which substantially conforms to the physiology of the user's body at the point which the sensor is to be used.

A further object of the invention is to provide an improved sensor for use in an oral, vaginal or anal probe, which permits accurate sensor readings of a body condition to be taken in vivos.

A further object of the invention is to provide an improved chemically activated strip for use in an oral, vaginal or anal probe, which permits accurate indications of a body condition to be taken in vivos.

Another object of the invention is to provide a probe having one or more sensors adapted to sense an indication on a chemically activated paper, plastic, metal, glass or other substrate which is coated or uncoated, so as to provide the desired indication of a particular body condition upon contact with a patient's body tissues or fluids.

A further object of the invention is to provide a probe having one or more sensors which may be operated in conjunction with a number of different types of strip media which provide indications thereon which are representative of differing body conditions.

Another object of the invention is to provide a probe having an end portion sized for insertion into a subject's mouth, vagina or anus, and which includes a number of sensors which may be operated either singularly or plurally, in various selected combinations, or simultaneously to sense various body characteristics of the subject which are indicative of different body conditions.

Another object of the invention is to provide a vaginal probe used to sense a number of different and continuous possible body conditions in a human subject by the selective activation and deactivation of different sensors disposed thereon.

A further object of the invention is to provide a vaginal probe which may be used to sense body characteristics of an animal, and which includes a transponder transmitter and/or signal receiver which permits the probe to be identified for use with an individual animal having a specific receiver or transponder signal transmitter.

In furtherance of at least some of the foregoing objects, the invention provides a probe having at least one, and preferably a number of sensors which are used to determine the status of one or more different body conditions of a human or animal subject. Possible body conditions to be assessed by the probe include by way of non-limiting examples, the presence of the viable egg in a female subject, whether or not a female subject is ovulating or has ovulated, an indication of a probable pregnancy or menopause, hormone imbalance, infertility and/or the presence of a possible disease or infection in the subject, such as yeast infection, HIV, thyroid disorders, AIDS, cancer or hepatitis.

In use of the probe, the sensors are operable to sense one or more of the subject's body characteristics which provide indications of the body condition to be determined. For example, the sensors may be used to sense body temperature, inhibin, the pH level of sensed fluids, male or female hormone levels such as Luteinising hormone (LH) level of vaginal fluids, cervical mucous density, estrogen levels, progesterone levels, estradiol levels, vaginal cavity pressures, follicle stimulating hormone (Fsh) levels, blood colouration, and/or human chorionic gonadotropohin (hCG) hormone levels. Data collected by the sensors is then processed and analyzed to determine the status of the particular body condition, and the calculated information respecting the status of the subject's body condition is output on a light emitting diode (LED), liquid crystal display (LCD), voltage or current display, or by an audio speaker provided as part of the probe, and/or presented on a computer screen which is linked to the probe.

Most preferably, the probe has an elongated end portion which is sized to permit insertion into the subject's vagina. The insertable end portion is configured to releasably retain a medium which is adapted to provide an indication of the sensed body characteristic thereon. Suitable media include flexible, rigid or semi-rigid paper, plastics such as Mylar™ and Lexan™, metal or other suitable substrates, which may be in the form of strips. The strips may optionally be chemically treated or coated. For example, the indication may consist of a change in current flow, resistivity, voltage or conductivity along the strip, or changes in colour, clarity, opaqueness or shading of or along part or all of the strip. It is to be appreciated that the indication may result from a chemical change or reaction between the patient's body fluids, such as saliva, cervical

mucous, vaginal fluid, blood or urine, and the strip, or the partial or complete dissolutions of coatings applied over the strip. Optical sensors such as infrared (IR), ultraviolet (UV) light or laser and/or current, voltage, resistance or conductivity sensors are provided at locations on or in the probe housing so as to provide a reading of the resulting indication on or along the strip. Data from the sensors is electronically transmitted to integrated circuitry for analysis and output.

The insertable portion of the probe may also be contoured so as to have a complementary shape to fit the physiology of the subject's vagina, anus or mouth depending on where the sensor is to be placed. For example, where the sensor is to be used vaginally on a human subject, the probe may include a contoured portion which is characterized by a gently curving concave surface. The concave surface curves in a longitudinally extending arc and is configured for placement against the anterior wall of a woman's vagina. In this manner, the insertable end portion of the probe follows the natural curvature of the anterior vaginal wall, ensuring close contact between the probe and the body tissues which make up the subject's vaginal walls.

The replaceable strip media may be releasably secured to the probe in a number of possible manner. For example, the strip media may be provided with an adhesive backing which enables it to be secured in place along part of the insertable end portion of the probe. Optionally, the probe may be provided with a groove or depression having a complementary shape to the strip media to enable its simplified positioning, and ensuring that indicating regions on the strip locate the desired position relative to the strip sensors.

The probe could alternately be provided with a covering cap used to retain the strip in the desired position, sandwiched at least partially between the cap and the remainder of the probe. The covering cap could be configured for mechanical coupling to the probe by means of a threaded coupling slot engagement or snap fit arrangement. If desired, fluid flow slits and/or grooves could be formed in the covering cap to assist in directing body fluids towards openings therein which lead towards the indicating regions in the strip. In an alternate embodiment, the insertable portion of the probe may also define a slot which extends into the probe interior. The slot is sized to receive and releasably retain the strip medium therein. With this arrangement, a

sensor, such as a light sensor, IR sensor, UV sensor, photovolatic cell, resistance sensor, voltage and/or current sensor, or conductivity sensor is housed substantially within the probe interior and is used to detect indications on or electron flow along the medium.

The optical sensors may include transmitter and receptor elements disposed on the same or opposite sides of the medium to detect the indicating colour, opacity or the like. Where the strip medium is releasably secured to the outer surface of the probe, the optical sensor would include transmitter and receptor elements disposed on the same side of the strip. If desired the probe may include electronics which permit the optical sensor to be used with different strip medium to provide indications of different body conditions.

Other secondary sensors may also be provided along the insertable end portion of the probe. Such secondary sensors may include temperature sensors as well as biosensors, infrared (IR) sensors, electrical resistance sensors, electromagnetic radiation sensors, chemical sensors, photovolatic sensors, photoconductors and detectors, or thermal imaging arrays. Other types of sensors may also be used. The sensors are electronically coupled to the integrated circuitry which is either housed within the probe housing itself, and/or an external computer by means of either a connecting cable and interface port or by wireless transmitter and receiver.

Most preferably, the insertable end portion of the probe is configured to ensure good contact between the probe sensors and the subject's body fluids and/or tissues. This advantageously eliminates air pockets and false readings, and ensures more accurate sensor readings.

Where the probe is to be used for veterinary applications, the insertable end portion of the probe may be formed having a larger or smaller size, depending upon the animal with which the probe is intended to be used. In veterinary applications, the probe preferably also includes a transponder signal receiver adapted to receive a transponder signal from a transponder signal transmitter mounted on an animal collar or tag. In this manner, the probe may be electronically

coded for use with a particular animal, so as to minimize the possibility of disease transmission to other animals.

Accordingly, in one aspect the present invention resides in combination a probe for sensing a body condition of a human or animal subject and a disposable medium adapted to provide an indication thereon which is representative of said body condition when contacted with body fluids or tissues from said subject,

said probe including an end portion sized for insertion into said subject's mouth, anus or vagina, and a sensor adapted to sense said indication on said medium while said medium is secured to said probe and generate data signals representative of said indication,

an attachment mechanism used to releasably secure said disposable medium to said end portion so as to permit its insertion therewith into said subject's mouth, anus or vagina,

an integrated circuit electronically linked to said sensor for processing said data signals.

In another aspect, the present invention resides in combination a probe for sensing a body condition of a human or animal subject and a disposable medium adapted to provide an indication thereon representative of said body condition when contacted with body fluids from said subject,

said probe having an end portion sized for insertion into said subject's mouth, anus or vagina,

a slot formed in said end portion and extending into an interior of said probe, said slot sized to receive said medium therein,

a sensor disposed proximate to said slot, said sensor adapted to sense said indication on said medium and generate data signals representative of said indication,

an integrated circuit electronically linked to said sensor for processing said data signals.

In a further aspect, the present invention resides in combination a probe for sensing a body condition of a human or animal subject and a strip medium having an activatable portion adapted to provide an indication thereon which is representative of said body condition when contacted with body fluids from said subject,

said probe having an end portion sized for insertion into said subject's mouth, anus or vagina,

an attachment mechanism releasably securing said medium to said end portion so as to permit its insertion therewith into said subject's mouth, anus or vagina, the attachment mechanism comprising a removable cover sized for insertion over at least part of said insertable end portion,

said medium being releasably retained at least partially by said cover and said part of said insertable end portion, said cover permitting substantially unrestricted flow of said body fluids therethrough to said activatable portion when said strip medium is retained thereby.

In a further aspect, the present invention resides in a probe for use with a disposable medium having an activatable portion providing an indication of determining a body condition of a human subject, the probe comprising,

a generally cylindrical housing elongated along a longitudinal axis and having a first end portion sized for insertion into the subject's mouth, vagina or anus, and a second end portion,

an attachment mechanism for releasably securing said medium to said first end portion so as to permit its insertion therewith into said subject's mouth, vagina or anus,

at least one sensor disposed along said first end portion for sensing said indication and generating data signals representative of said sensed body characteristic,

an integrated circuit for receiving said data signals from said at least one sensor and for processing said data signals, and

an output electronically linked to said integrated circuit for outputting information representing the status of said body characteristic.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is now made to the following detailed description taken together with the accompanying drawings in which:

Figure 1 is a schematic front view of a vaginal probe for use on a human subject in accordance with a preferred embodiment of the invention;

Figure 2 is an enlarged exploded view of the end tip of the probe shown in Figure 1 showing the manner of securing a replaceable strip thereto;

Figure 3 is an enlarged cross-sectional view of the end tip of the probe shown in Figure 1 taken along lines 3-3;

Figure 4 illustrates schematically a side view showing the placement of the probe of Figure 1 during sensor operation;

Figure 5 illustrates schematically a side view of an end tip of the probe in accordance with a second embodiment of the invention;

Figure 6 is a schematic view of a probe for use on an animal subject in accordance with another aspect of the invention;

Figure 7 is a schematic view of a probe in accordance with a further aspect of the invention;

Figure 8 is an enlarged cross-sectional view of the insertable endmost tip of the probe shown in Figure 7; and

Figure 9 is an exploded schematic view of the end tip of the probe in accordance with a further embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Reference is first made to Figures 1 to 3 which show a vaginal probe 10 which is operable to determine the current status of a number of different body conditions of a human

female patient, including whether or not the patient has conceived, the presence of possible diseases or infections, pre and/or post menopause in females, or whether or not the patient has ovulated, is currently fertile or ovulating or is about to ovulate.

As seen best in Figure 1, the probe 10 comprises a molded housing 12 which is formed having a generally cylindrical shape and which is elongated in a longitudinally direction. The housing consists of a semi-rigid rubber or plastic insertable end portion 14 which is sized for insertion into a woman's vagina 20 (Figure 4) and an external end portion 16 along the exterior of which are provided operational controls 21 used to operate the probe 10 and a liquid crystal display (LCD) 22. The controls 21 include switches used to turn the probe 10 off or on, as well as switches used to select a specific body condition to be sensed. As will be described, while controls 21 and a display 20 are provided, the probe 10 is most preferably adapted for cordless use and is housed within a base 39 which includes controls 40 as well as a primary LCD 41.

The insertable end portion 14 has a maximum lateral thickness T_1 (Figure 1) selected at between about 0.5 and 2 cm, and preferably about 1 cm. The insertable end portion 14 extends from an endmost tip 24 rearwardly to merge into the exterior end portion 16, and has an overall axial length of between about 5 and 15 cm. As will be described hereafter with reference to Figure 4, the length of the insertable portion 14 is selected so that when the end portion 14 is fully inserted into the patient's vagina 20, the tip 24 locates immediately adjacent to and most preferably in contact with the patient's cervix 26 (Figure 4).

The probe 10 is used in conjunction with a disposable generally rectangular flexible strip 34. The strip 34 is formed as a coated cellulose, Mylar™, or Lexan™ or other plastic substrate. A sensing region 35 (Figure 2) of the strip 34 is provided with a reactive die or other suitable chemical coating to provide a visual indication such as colour, shading, clarity or opaqueness, which is representative of one or more sensed body conditions when contacted with vaginal fluids. For example, the coating may change to a particular colour when contacted with a particular hormone concentration. Alternately, part of the coating may dissolve when contacted

with fluids having a predetermined pH. Most preferably, the strip 34 also includes a control region 35' (Figure 2) which provides a base line or control reading used to calibrate the probe 10.

Figure 2 shows the probe 10 as including a removable cap 28 which is configured for positioning over the end tip 24. The cap 28 is formed having a hollow thimble-like construction and is removably secured over the end tip 24 of the probe 10 by the threaded engagement between internal threads 29 formed about the open end of the cap 28, and complementary formed external threads 30 formed about the probe housing 12. The cap 28 defines an inner cavity which is configured to substantially correspond to the profile of the end tip 24 and which further defines a narrow rectangular recess or positioning groove 32 formed along its interior surface. The groove 32 has a complementary profile to that of the replaceable strip 34. As is shown, the positioning groove 32 is located so that when the cap 28 is secured over the tip 24, the strip 34 locates along a forwardmost side portion of the insertable portion 14.

Figures 1to 3 show best the tip 24 as including a pair of sensors 36,38. Each sensor includes, respectively, an infrared emitter 36a,38a (Figure 2), such as an infrared diode adapted to output plused, broadband IR energy, and an infrared receptor 36b,38b (Figure 2), such as a photodiode synchronized to receive the pulsed IR energy. The cap 28, recess 32 and sensors 36,38 are positioned so that when the cap 28 is secured to the remainder of the probe 10 through coupling of the threads 29 with threads 30, the strip 34 is secured substantially within the positioning groove 32 with the sensing region 35 of the strip 34 immediately adjacent to the emitter and receptor 38a,38b and the control region 35' of the strip 34 immediately adjacent the emitter and receptor 36a,36b, as for example is shown in Figure 3.

Slits and/or apertures 33 are formed through the cap 28 adjacent the sensors 36,38, to permit the substantially unrestricted flow of vaginal fluids through the cap 28 to the recess 32 and strip media 34. The apertures 33 advantageously also permit the visual inspection of the sensing region 35 and control region 35' in the qualitative analysis of the strip 34.

Each of the sensors 36,38 are selected to provide data signals to an integrated circuit 64 which are representative of a resulting colour, shading, clarity or opacity indication on the strip media 34. Sensor 36 is provided as a "control" sensor used to read the control region 35' and establish a base line reading. Sensor 38 is used to sense the indication of the exposed portion of the strip.

The integrated circuit 64 initially receives all input data signals from the sensor 38 and accepts data within specified limits, converting the input data signals to digital data. The circuit 64 then calculates all input data signals and yields a decision with respect to the sensed body characteristic. Data signals from the sensor 36 are similarly input, and the integrated circuit 64 challenges all decisions for exceptions and validates the decision, and then displays results. The integrated circuit 64 further records the input data signals, and exceptions to the data and calculated decisions for closer therapeutic scrutiny of any specific session.

It is to be appreciated that the sensor configuration shown in Figures 1 to 3 is advantageous in that it permits the replacement and substitution of the strip 34 after each test. Following each test, the cap 28 is removed by unscrewing the threads 29,30 and the strip 34 replaced. The present invention advantageously allows different types of strips 34 to be used with the same probe 10, for sensing different human characteristics. For example, following the use of the coated Mylar strip 34 to sense hormone levels, a strip formed from litmus paper may be used to sense the pH of vaginal fluids.

Six longitudinally spaced apart secondary sensors 42,44,46,48,50,52 are positioned axially aligned with each other along a medial portion of the insertable portion 14 of the probe 10. By way of non-limiting examples, suitable secondary sensors for use with the probe 10 would include photovolatic sensors such as those manufactured by Sensors Unlimited, Inc., electro-optic detectors including photoconductors, photodiodes, thermophile and pyroelectric sensors such as those sold under the name EPNE™ by Abtech Laboratories Products, as well as chemoresistance sensors and bio-analytical biotransducers. It is to be appreciated that the positioning of the secondary sensors 42,44,46,48,50,52 is most preferably selected to conform to

the curvature of part of the patient's anterior vaginal wall 90 (Figure 4) to ensure that, when inserted, the secondary sensors 42,44,46,48,50,52 are maintained in close contact therewith. This advantageously and substantially eliminates any air pockets between the secondary sensors 42,44,46,48,50,52 and the patient's vaginal tissues which may give rise to false sensor readings.

Sensor 42 is a biosensor used to sense human chorionic gonadotrophin (hCG) levels in the patient's vaginal fluids. It is generally believed if pregnant, hCG numbers will tend to increase following pregnancy. The probe 10 and either the integrated circuit 64 may thereby be used to analyze two consecutive hCG tests immediately following ovulation as an indicator of unlikely pregnancy. hCG hormones produced during pregnancy are detectable in the blood, urine or cervical mucous 1 to 2 days after implantation (10 days after ovulation). This hormone increases rapidly in the first trimester, reaching a peak 60 to 80 days after fertilization; then drops off quickly to 10 to 30% of the peak value for the rest of the pregnancy. It serves to maintain progesterone production by the corpus luteum in the early part of pregnancy. By the time hCG drops at the beginning of the second trimester, the placenta can make sufficient progesterone to maintain the endometrium. In general, a sensed hCG level of less than 5 mIU/ml would be generally indicative that the patient was not pregnant.

Sensor 44 comprises an ultrasound sensor used to sense Luteinising hormone (LH) levels. As disclosed in U.S. Patent No. 5,209,238 to Sundhar, by ascertaining the amplitude of reflected ultrasonic energy from vaginal tissues, it is possible to ascertain the presence of LH levels in the patient. These levels in turn may be used to correlate whether or not the patient has or may be currently ovulating.

Sensor 46 is an estrogen biosensor which is used to ascertain the levels of one or more of estradiol, estrone, and estriol in the patient's vaginal fluids. Sensor 48 also consists of a biosensor used to sense progesterone levels in the patient's vaginal fluids, and may be used in conjunction with sensor 46 to evaluate whether or not the patient has conceived or about to start ovulation. Like estrogen, progesterone is made in the ovaries. Progesterone production begins rising at ovulation and increases rapidly until it reaches an average production of about 22

milligrams per day. If an egg is not fertilized, progesterone production (as well as that of estrogen) falls quickly. This initiates the menstrual flow. Progesterone is necessary for the survival of a fertilized egg, the resulting embryo, and the fetus throughout gestation. It is also the precursor of other steroid hormones including cortisol, aldosterone, estrogen, and testosterone. Progesterone has many other functions, among them protecting against breast fibrocysts, helping the body use fat for energy, and helping to normalize blot clotting and blood sugar levels.

Sensor 50 operates as either a UTI sensor or pH sensor to measure acidity or alkalinity via the electrical potential of the vaginal fluids. Sensor 52 consists of biosensor used to sense the presence of a possible disease in the patient. In addition, Figure 4 also shows the probe 10 as also including a basal body temperature (BBT) sensor 56.

The primary sensors 36,38, as well as the secondary sensors 42,44,46,48,50, 52,56 are each electronically coupled to the integrated circuit 64 (Figure 1) contained within the housing 12 by an optical fiber coupling and/or lead wires 66. Power to the probe 10 and sensors 36,38,42,44,46,48,50,52,56 is supplied by an internal battery 70. The integrated circuit 64 may also include memory used to store previous data from the patient by date, time and type of data, and permit a comparison of stored data from currently sensed data. Optionally, one or more amplifiers 71 with signal processing capability may also be housed within the external end portion 16 of the probe 10 for use in amplifying the sensor signals. The wires 66 also electronically link the controls 21 and LCD 22 to the integrated circuit 64, battery 70 and to the base unit 39 via an interface port 72. In this manner the controls 21 and/or 40 are used to selectively actuate and/or receive data from one or a combination of sensors 36,38,42,44,46,48, 50,52,56 depending upon the patient's body condition to be determined. The controls 21 are also configured to automatically turn the probe 10 to a "power off" state after a predetermined period of over-use, to preserve battery 70 life.

In a preferred embodiment, the probe 10 is designed for both portable as well as in clinic use by both professional staff as well as by the patent directly. In addition to the internal battery

70, the integrated circuit 64 may also be connected to a computer 75 (Figure 4) via the interface port 72 located on the external end portion 16 of the probe 10. The interface port 72 permits the probe 10 to be linked to a personal computer 75 either wirelessly or through a control cable 76 in the manner shown in Figure 4. The computer 75 may be used in place of the base unit 39 in the control of the probe 10 and/or to input to and receive output from the probe 10, visually indicating the status of the patient's body condition which is sensed. Patient data and medical history is preferably also stored in the computer 75, including for example, information as to the patient's name, social security data, age, known allergies. Optimally, the personal computer 75 may also be used to store data from previous diagnostic tests to permit a user to chart changes in the sensed body characteristics and, for example, provide an indication of a likely pregnancy or the like.

The operation of the probe 10 is shown best with reference to Figure 4. The strip media 34 is positioned within the cap positioning groove 32. The cap 28 is coupled over the probe end tip 24 and secured in place by the engagement between the threads 29,30. The insertable end portion 14 of the probe 10 is then placed into the patient's vagina 20. The insertable end portion 14 is inserted into the subject's vagina 20 so that the endmost tip 24 locates adjacent to the outer end of the patient's cervix 26, and with the external end portion 16 maintained external to the patient. Where the probe 10 is used vaginally on a human female, the probe 10 is positioned so that the sensors 42,44,46,48,50,52 are moved into juxtaposition with the anterior vaginal wall 90 of the patient's vagina 20. In this position, the basal body temperature sensor 56 locates in contact with the posterior vaginal wall 90. When the probe 10 is inserted into a subject's vagina 20, if the cervix 26 is closed the end tip 24 may be used to apply pressure against the closed cervix 26 to facilitate the escape of fluids therefrom. With the probe 10 fully inserted, mucous from the cervix 26 may pass through the cap apertures 33 to activate the strip 34. The sensors 36,38 are then operated to sense indications, such as change of colour, opacity, clarity, or shading on the strip at both the exposed sensing portion 35, as well as the control portion 35'. The data from the sensors 36,38 is thereafter processed by the integrated circuit 64 or exported to either the base unit 39 or the personal computer 75 (Figure 4) for display and/or analysis. Following a determination of the sensor reading, the probe 10 may optionally be removed and a

different strip media adapted to provide an indication of a different body characteristic may be inserted into the cap positioning groove 32.

The secondary sensors 42,44,46,48,50,52,56 are also actuated by means of either the controls 21 on the exterior portion 16 of the probe 10, (or via the computer 75 if the interface port 72 is used) to sense the desired body characteristic. It is to be appreciated that the sensors 42,44,46,48,50,52,56 may be operated independently depending upon which body condition is to be analyzed, or simultaneously for an overall diagnostic analysis. Alternately, all of the secondary sensors 42,44,46,48,50, 52,56 may be continuously operated and the integrated circuit 64 used to selectively screen and analyze data signals therefrom, depending on the body condition to be sensed. Following their activation, data received from the sensors 42,44,46,48,50,52, 56 is processed by the integrated circuit 64 (or by the computer 75) to determine the status of the particular body condition, and the status of the body condition in their output to the user via the LCD 22 or the display 41. Data output from each sensor 42, 44,46,50,52,56 is also compared and validated against each other to ensure an accurate and true reading by the probe 10.

While the embodiment of the invention shown in Figures 1 to 4 illustrates the releasable cap 28 as securing the strip media 34 along a forwardmost side of the probe 10, the invention is not so limited. If desired, the cap 28 could secure the strip 34 directly over the endmost tip 24 of the probe 10. Alternately, the strip 34 could be provided along a lowermost side of the probe, depending upon the characteristic to be sensed. Similarly, while the cap is shown as being held in place by a threaded coupling, other means of securing the cap 28 in place will also become apparent. By way of non-limiting examples, the cap 28 could be held in position by friction engagement between a flange and a complementary shaped slot, by press fitting, or by mechanical fasteners such as tabs, pins, clips or the like.

Although Figure 1 illustrates the cap 28 as including the positioning groove 32, it is to be appreciated that the groove 32 could equally be provided in the surface of the probe housing 12 or omitted without departing from the spirit and scope of the invention. Alternately, the probe 10

or cap 28 may be formed having a key or projection (not shown) configured to engage a complementary shaped recess in the strip 34 to ensure its correct positioning.

Figure 5 shows a modified probe end tip 24 in accordance with a further embodiment of the invention in which like reference numerals are used to identify like components. In Figure 5, the cap 28 is omitted. The strip 34 is provided with an adhesive backing 78 which is used to releasably secure the strip 34 to the probe 10. The end tip 24 is provided with a guide recess 80 which extends across the apex of the tip 24 and which is formed having a substantially complementary size to the strip media 34. As with the embodiment described with reference to Figures 1 to 4, a control sensor 36 consisting of an IR emitter and IR receptor and a fluid sensor consisting of an IR emitter and IR receptor are provided in the probe housing 12 immediately adjacent the recess 80 so as to sense respectively, the indications on both the control region 35' and sensed region 35 on the strip media 34.

Figure 5 further shows the probe 10 as including a laser reader 82. The reader 82 is configured to identify visual indicia such as a bar code 84 which is printed on the strip 34. The laser reader 82 is connected to the integrated circuit 64 via the lead wire 66, and may be used to automatically calibrate the probe 10 for sensing a particular body characteristic in response to the bar code information 84.

Figure 6 illustrates a modified probe 10 for use in veterinary applications, and wherein like reference numerals are used to identify like components. Like the apparatus shown in Figure 1, the probe 10 of Figure 6 is adapted to be used as either a stand alone unit, or in a clinical environment if connected to a computer in the manner shown in Figure 4. In a more economical model, however, the probe 10 could be provided without the computer interface port 72 restricting the probe 10 to portable in field use.

Figure 6 further shows the probe cap 28 as including a number of fluid directing flow grooves 86. The fluid flow grooves 86 are formed in the cap 28 and extend in a generally longitudinal orientation towards the apertures 33. The grooves 86 preferably have approximate

dimensions of 0.5 to 1 mm in both lateral width and depth and permit the substantially unrestricted movement of fluids therealong. The flow grooves 86 assist in directing any fluids directly into the cap apertures 33 to ensure complete activation of the strip media 34. It is to be appreciated that although not shown, flow grooves or slits could also be provided within the cap 28 of the vaginal probe 10 described as being for human use with reference to Figure 1.

Although not essential, the probe 10 of Figure 6 is typically larger in size than the probe 10 of Figure 1 described for human use. The probe 10 of Figure 6 could optionally include fewer or more secondary sensors 42,44,46,48,50,52,56 depending upon the characteristics to be sensed. The probe 10 is additionally provided with an internal transponder signal receiver 92 which is electronically linked to the LCD display 22, integrated circuit 64 and lead wires 66. The transponder signal receiver 92 is adapted to receive a signal from a transponder signal transmitter 94 which is mounted on a collar 96 to be secured to a subject animal. The transponder signal receiver 92 advantageously permits the user to identify precisely which animal out of a herd is to be diagnosed with the probe 10. Where highly contagious diseases may be present in a herd, the transponder signal receiver 92 is used to isolate the probe 10 for use with the infected animal, minimizing the likelihood of cross-infection between the herd animals. In addition, the probe 10 integrated circuit 64 is selectively operable for each coded transponder signal to provide a stored data base of diagnostics for a number of different herd animals.

Although the preferred embodiment of the invention illustrates the probe as having two primary strip reading sensors 36,38, six secondary sensors 42,44,46,48,50,52 and a basal body temperature sensor 56, the invention is not so limited. If desired, the probe 10 could equally include fewer or more primary and/or secondary sensors without departing from the spirit and scope of the present invention. Similarly, while Figures 1 and 5 illustrate the strip media 34 as being secured to the probe housing 10 by either an adhesive backing 78 or through the mechanical clamping of a cap 28, the invention is not so limited and other means of securing the strip media to the probe 10 during in vivos data collection are also possible. Figures 7 and 8 show a differing sensor arrangement in which like reference numerals are used to identify like components. Figures 7 and 8 show best the probe 10 as including a modified sensor arrangement

at its endmost tip 24. The end tip 24 is provided with an inwardly extending rectangular slot 120 which extends between 1 and 2 cm inwardly into the interior of the probe housing and which has a width of between about 0.5 and 4 mm. The slot 120 is sized to releasably receive therein a disposable fluid absorbent litmus paper strip 122 as the replaceable strip media.

Like the probe 10 of Figure 1, the probe 10 of Figure 7 is adapted for cord free operation and includes a rechargeable battery 110 which is charged by means of a power base unit 112. The base unit 112 is adapted to be plugged directly into a wall outlet and includes an internal transformer 114 used to regulate the power supply and used to provide charging power to the battery 110, as well as microprocessor 116. While the embodiment of the invention shown in Figure 1 illustrates the probe housing 12 as including controls 21 and a liquid display 22 in addition to the base unit controls 40, it is to be appreciated that the probe 10 could be preprogrammed from the base unit 39 itself.

Rearwardly from the tip 24, the insertable end portion 14 is provided with a contoured portion 136 which is configured to provide a complementary shape and size to the physiology of the patient's vagina 20. The contoured portion 136 includes a concave surface which curves gently as a longitudinally extending arc a distance of approximately 5 to 8 cm. The curvature of the contoured portion is generally complementary to the curvature of part of the patient's vagina 20 (Figure 4). Secondary sensors 44,46,48 are preferably provided as a longitudinally extending array along the portion 136, to maintain their close contact with the patient's vaginal walls.

The optical sensor used to identify the visual indication on sensing region 35 (Figure 8) of the strip 122 is positioned at the distal end of the slot 120. The optical sensor consists of an infrared emitter 126 and an optical receptor 128 positioned upon opposite sides of the slot 120 so as to locate on each side of the strip 122 when positioned therein.

In a simplified embodiment, the paper strip 122 consists of litmus paper which changes colour having regard to the hCG level in a patient's vaginal fluids. In use, a strip 122 adapted to provide the desired indication representing the hCG or other hormone level is inserted into the

slot 120 so as to be frictionally retained thereby and the probe 10 is inserted into the patient's vagina. As the distal end of the probe 10 is inserted into the patient's vagina, fluids from the vagina are absorbed by the paper strip 122. The absorbed fluids activate the strip 122 and provide a colour indication representative of the body condition sensed. The infrared emitter 126 and receptor 128 are then activated to sense the colour indication on the indicator portion 35 of the strip 122 which is positioned therebetween.

If insufficient fluid or cervical mucous exists, the subject may alternately urinate on or apply blood to the strip 122 and then insert the strip 122 into the slot 120 for analysis.

While the embodiment of the invention Figures 7 and 8 illustrate the infrared emitter 126 and receptor 128 as being positioned on opposite sides of the strip 122, the invention is not so limited. If desired, the infrared emitter and receptor 126,128 could be positioned on the same side of the strip and operated to measure reflected light.

In an alternate embodiment shown in Figure 9, in which like reference numerals are used to identify like components, the strip 34 may be fixedly secured to the cap 28 for either reuse or with the entire cap 28 and strip 34 assembly disposed after each use. Where the cap 28 is disposable with the strip 24, the cap 28 may be formed from glass, plastics, spagnum paper or mixtures thereof for more economical manufacture. With this construction, the cap 28 is interchangeable and most preferably is configured to automatically preprogram the probe 10 to recognize the strip 34 mounted therein. In one simplified construction, a series of switches 102,104,106 are provided about the end tip 24 connected to the integrated circuit by the wires 66. The activation of a particular switch 102,104,106 causes the integrated circuit to automatically preprogram the probe sensors 36,38 for operation with a particular pre-selected strip 34. The cap 28 is provided with an internally disposed boss 110 positioned to activate the particular switch corresponding to the strip 34 retained therein, when the cap 28 is fully secured in place.

The strip 34 could also be provided with a number of separate indicator portions, each responsive to different body conditions. With such a strip, a number of optical sensors used to

read the separate indicator portions, or those of different strips may be movably provided within the probe housing 12. For example, sensors disposed within the housing may be selectively moved into an operational reading position by mounting on a manual or motor driven turn table, so as to rotate into the desired reading position depending on the type or portion of the strip 34 to be read.

While the preferred embodiment of the invention discloses the strip media as comprising coated Mylar™ or litmus paper strips used to determine hCG or pH concentration, other media including metals, papers, glass or plastics and/or other body conditions may also be used with the probe. Similarly, while an infrared emitters 38a and receptors 38b may be preferred, other lasers, UV or visible light emitters and receptors may also be used without departing from the spirit and scope of the invention. Similarly, the strip 34 could provide a change in voltage, current, resistance or conductivity as an indication of the sensed body characteristic. With this arrangement, sensors measuring electrical resistance, voltage, current or conductivity along the strip could also be employed in place of optical sensors.

While the preferred embodiment of the invention illustrates the probe as including a series of longitudinally extending secondary sensors 42,44,46,48,50,52,56 the invention is not so limited. If desired, the secondary sensors could be provided in a lateral or staggered array, or omitted in their entirety.

Although the preferred embodiment of Figure 7 illustrates the probe 10 as including a contoured portion 132 as a preferred construction for use with a human subject, other contour configurations are also possible depending upon the intended animal subject with which the probe 10 is to be used.

While the embodiment shown in Figures 7 and 8 illustrate the litmus paper medium as being inserted through a slot 120 located at the distal most tip 24 of the sensor 10, the slot 120 could equally be provided as a longitudinally elongated slit extending along at least part of the length of the end portion 14.

Similarly, while the preferred embodiment discloses the probe 10 as sensing specific body characteristics of a subject, it is to be appreciated that different types of sensors may be used to sense other body characteristics depending on the body condition which is to be analyzed. Alternately, the probe 10 may be used to evaluate the condition of various foods and liquids to determine their suitability for consumption. In particular, the probe may be activated to determine the condition of meats, fish, poultry or other foods or liquids to detect the presence of diseases or potentially harmful bacteria.

The detailed description of the invention describes the sensing media as being in the form of an elongated rectangular strip. It is to be appreciated that the strip could be provided with almost any two dimensional or even three dimensional shape suitable for mounting on or in the probe housing.

While the preferred embodiment describes the probe housing as being from a semi-rigid rubber or plastic material, the probe housing could be formed partially or wholly from other materials including rigid plastics, composites, stainless steel or other metals.

Although the detailed description describes and illustrates various preferred embodiments, the invention is not so limited. Many modifications and variations will now occur to persons skilled in the art. For a more precise definition of the invention, reference may be had to the appended claims.

We claim:

1. In combination a probe for sensing a body condition of a human or animal subject and a disposable medium adapted to provide an indication thereon which is representative of said body condition when contacted with body fluids or tissues from said subject,

said probe including an end portion sized for insertion into said subject's mouth, anus or vagina, and a sensor adapted to sense said indication on said medium while said medium is secured to said probe and generate data signals representative of said indication,

an attachment mechanism used to releasably secure said disposable medium to said end portion so as to permit its insertion therewith into said subject's mouth, anus or vagina,

an integrated circuit electronically linked to said sensor for processing said data signals.

2. The combination as claimed in claim 1 wherein said medium comprises a paper, plastic, metal or glass substrate.

3. The combination as claimed in claim 2 wherein said substrate includes a coating and said sensor is disposed within said interior of said probe.

4. The combination as claimed in claim 1 wherein said sensor includes an optical emitter and an optical receiver.

5. The combination as claimed in claim 1 wherein said sensor is an infrared sensor.

6. The combination as claimed in claim 4 wherein said indication is selected from a change in colour, a change in opacity, a change in shading, and a change in clarity.

7. The combination as claimed in claim 1 wherein attachment mechanism comprises a removable cover sized for insertion over or in at least part of said insertable end portion, said medium being retained at least partially by said cover.

8. The combination as claimed in claim 1 wherein said attachment mechanism comprises an adhesive applied to at least one of said disposable medium and said end portion.

9. The combination as claimed in claim 1 wherein said attachment mechanism comprises a slot formed in said insertable end portion, said slot being sized to at least partially receive said medium therein in a friction fit manner.

10. In combination a probe for sensing a body condition of a human or animal subject and a disposable medium adapted to provide an indication thereon representative of said body condition when contacted with body fluids from said subject,

said probe having an end portion sized for insertion into said subject's mouth, anus or vagina,

a slot formed in said end portion and extending into an interior of said probe, said slot sized to receive said medium therein,

a sensor disposed proximate to said slot, said sensor adapted to sense said indication on said medium and generate data signals representative of said indication,

an integrated circuit electronically linked to said sensor for processing said data signals.

11. The combination as claimed in claim 10 wherein said medium comprises a paper, plastic, metal or glass substrate.

12. The combination as claimed in claim 11 wherein said medium comprises litmus paper and said sensor comprises an infrared emitter and an infrared receptor disposed within said interior of said probe.

13. The combination as claimed in claim 10 wherein said sensor includes an optical emitter and an optical receiver.

14. The combination as claimed in claim 10 wherein said sensor is an infrared sensor.

15. The combination as claimed in claim 10 wherein said indication is selected from a change in colour, a change in opacity, a change in shading, and a change in clarity.

16. The combination as claimed in claim 10 wherein said indication may be qualitative, quantitative or a combination thereof.

17. In combination a probe for sensing a body condition of a human or animal subject and a strip medium having an activatable portion adapted to provide an indication thereon which is representative of said body condition when contacted with body fluids from said subject,

said probe having an end portion sized for insertion into said subject's mouth, anus or vagina,

an attachment mechanism releasably securing said medium to said end portion so as to permit its insertion therewith into said subject's mouth, anus or vagina, the attachment mechanism comprising a removable cover sized for insertion over at least part of said insertable end portion,

said medium being releasably retained at least partially by said cover and said part of said insertable end portion, said cover permitting substantially unrestricted flow of said body fluids therethrough to said activatable portion when said strip medium is retained thereby.

18. The combination as claimed in claim 17 wherein said medium comprises a flexible metal, paper, plastic or glass substrate, and said indication is selected from a change in colour, a change in opacity, a change in shading, and a change in clarity.

19. The combination as claimed in claim 17 wherein said fluid comprises human cervical fluid and said body characteristic is selected from the group consisting of inhibin level, pH level, Luteinising hormone level, Fsh level, mucous density, estrogen level, progesterone level, and human chorionic gonadotrophin hormone level.

20. A probe for use with a disposable medium having an activatable portion providing an indication of determining a body condition of a human subject, the probe comprising,

a generally cylindrical housing elongated along a longitudinal axis and having a first end portion sized for insertion into the subject's mouth, vagina or anus, and a second end portion,

an attachment mechanism for releasably securing said medium to said first end portion so as to permit its insertion therewith into said subject's mouth, vagina or anus,

at least one sensor disposed along said first end portion for sensing said indication and generating data signals representative of said sensed body characteristic,

an integrated circuit for receiving said data signals from said at least one sensor and for processing said data signals, and

an output electronically linked to said integrated circuit for outputting information representing the status of said body characteristic.

21. A probe as claimed in claim 20 wherein attachment mechanism comprises a removable cover sized for insertion over at least part of said insertable end portion, said cover adapted to secure said medium retained at least partially between said cover and said part of said insertable end portion.

22. A probe as claimed in claim 21 wherein said cover further includes an aperture sized to permit substantially unrestricted movement of fluids from said patient's vagina, mouth or anus therethrough, said cover further including at least one groove to assist in directing said fluids to said aperture.

23. A probe as claimed in claim 20 wherein said body characteristic is selected from the group consisting of inhibin, pH level, Fsh level, Luteinising hormone level, estrogen level, progesterone level, and human chorionic gonadotrophin hormone level.

24. A probe as claimed in claim 21 wherein said disposable medium comprises a chemically activated strip fixedly secured to said cover.

25. A probe as claimed in claim 24 wherein said part of said insertable end portion includes a plurality of switches, each said switches being electronically linked to said integrated circuit and activatable to configure said probe for use in sensing a predetermined indication,

said cover including a boss thereon, wherein when said cover is inserted over said part of said insertable end portion so as to retain said strip, said boss activates a first one of said switches to configure said probe for use in sensing the indication on said retained strip.

ABSTRACT

A probe used to determine different possible body conditions of a human or animal subject includes an elongated insertable portion which is adapted for use orally, anally or vaginally, and along which are provided a number of biosensors and/or temperature sensors. The elongated portion is contoured so as to have a complementary shape to the physiology of the user's mouth, anus or vagina to ensure good contact between the probe sensors and the subject's body fluids or tissues. The probe is used in conjunction with a releasably retained strip medium which provides an indication of a sensed body condition thereon, and one or more sensors used to read the indications on the strip. In use, once the probe is inserted, body fluids will activate the strip medium in vivos ensuring more accurate biosensor readings.

Fig. 1

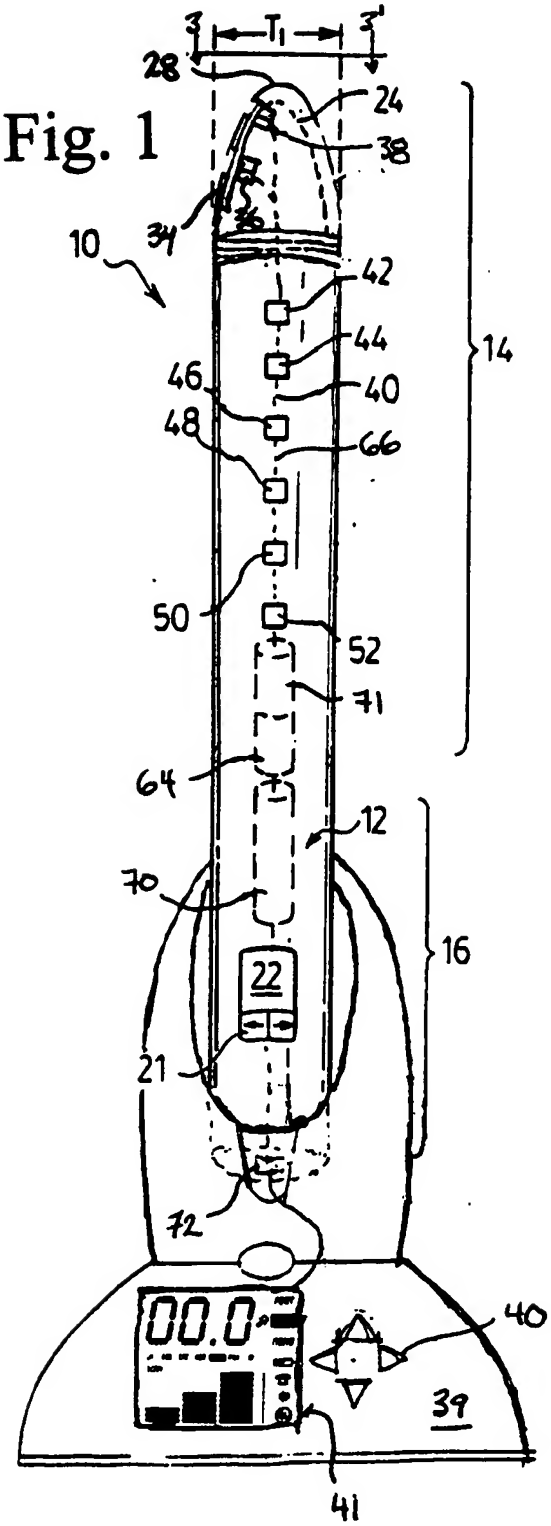

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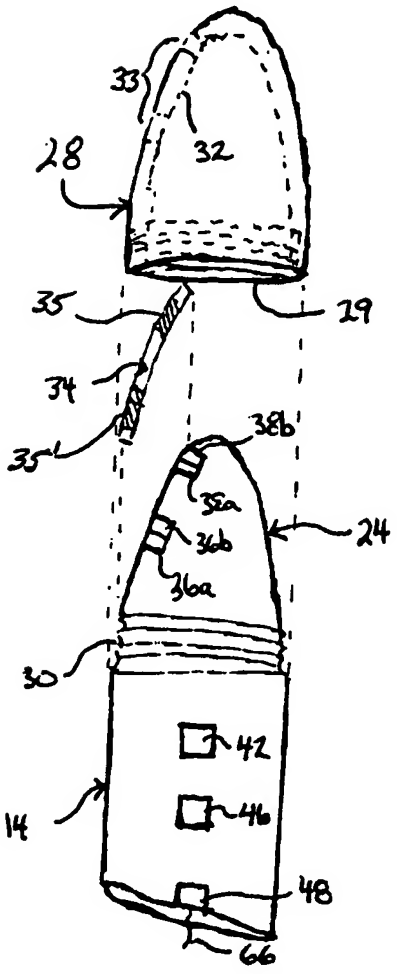
Fig. 2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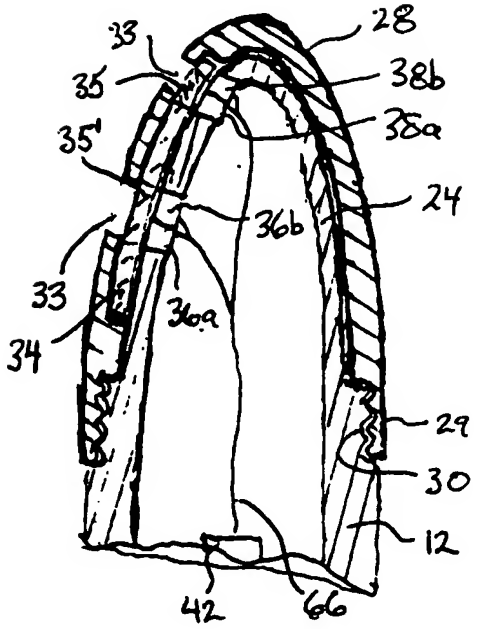
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Fig. 5

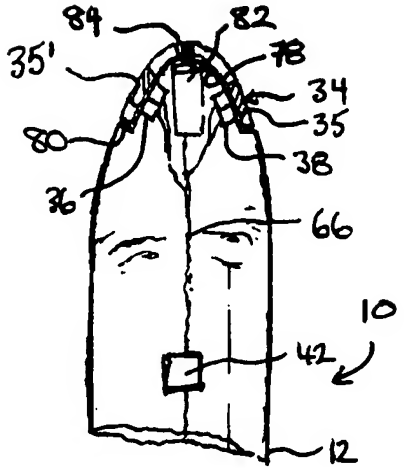
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Fig. 4

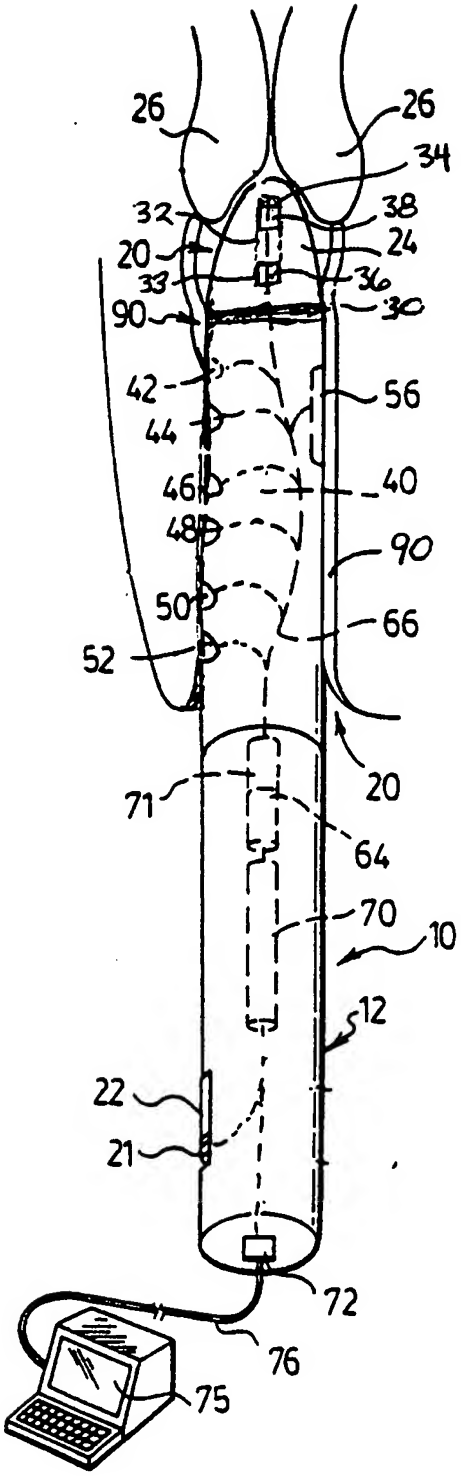
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Fig. 6

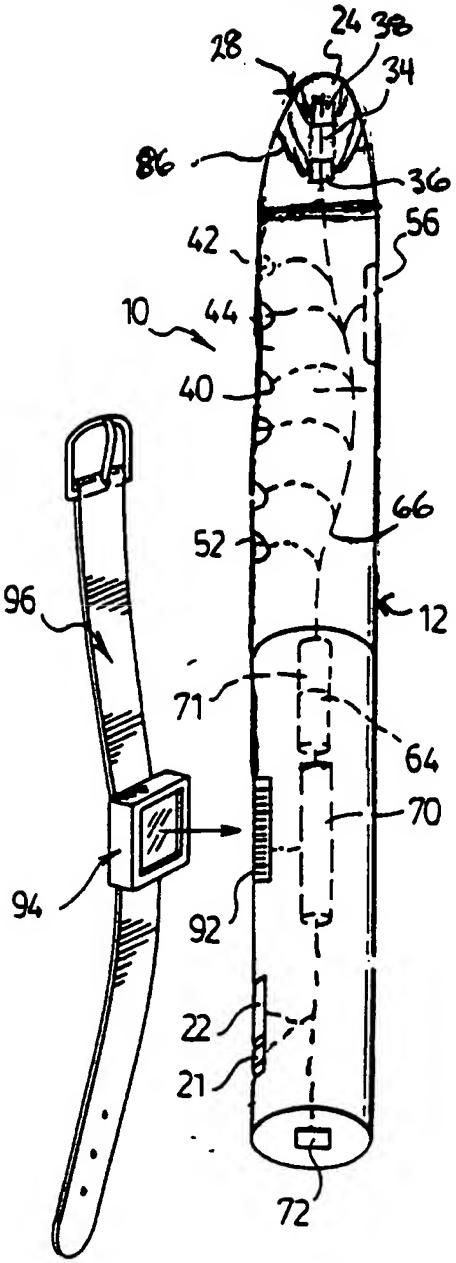
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Fig. 7

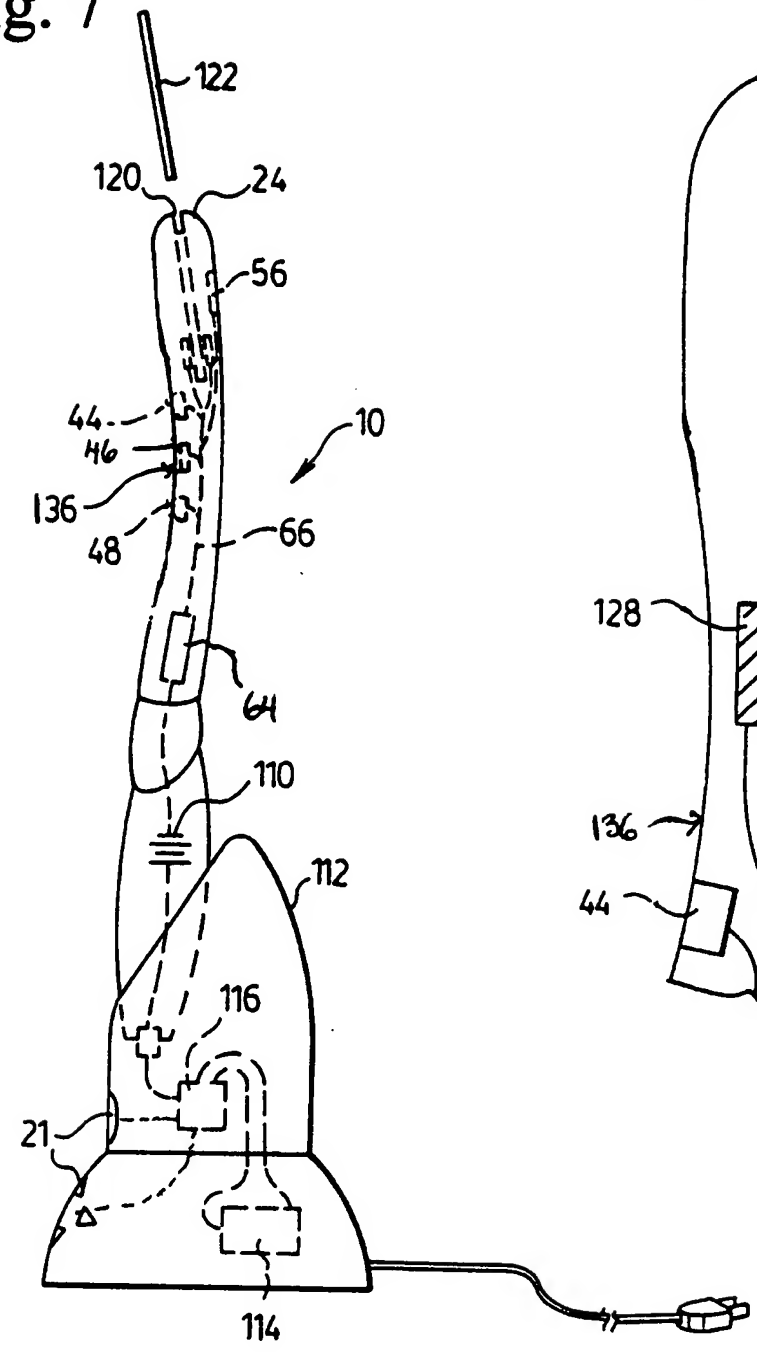
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Fig. 8

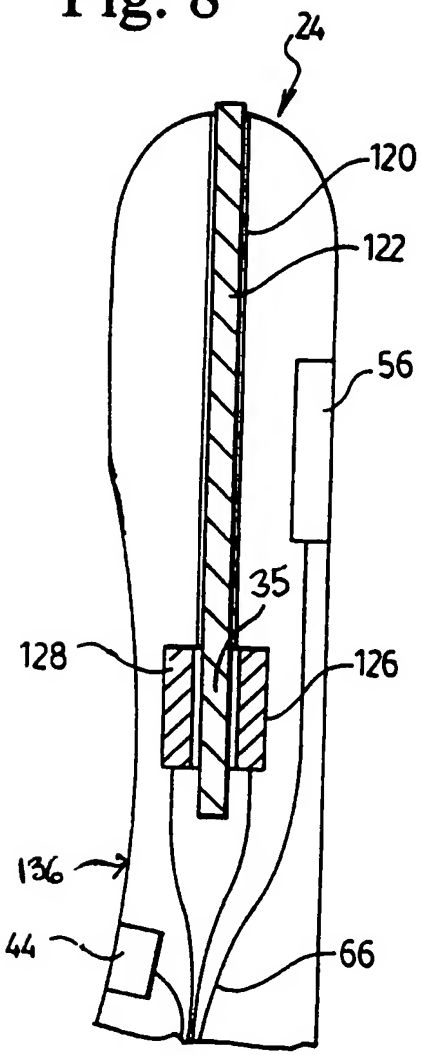
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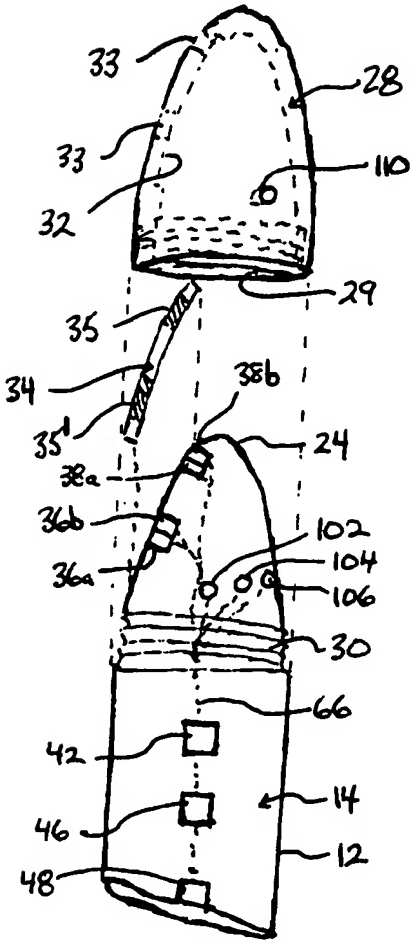
Fig. 9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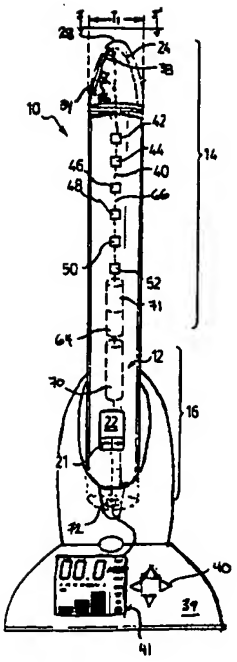
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